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| APPLICATION NO.                                | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|--|-------------|----------------------|---------------------|------------------|
| 10/566,878                                     | 02/02/2006  | Andries Van Es       | 08076200111         | 9964             |
| 545  | 7590        | 07/09/2007           |                     | EXAMINER         |
| ROGER PITT                                     |             |                      |                     | TSAY, MARSHA M   |
| KIRKPATRICK & LOCKHART PRESTON GATES ELLIS LLP |             |                      | ART UNIT            | PAPER NUMBER     |
| 599 Lexington Avenue                           |             |                      |                     | 1656             |
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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

|                              |                            |                  |
|------------------------------|----------------------------|------------------|
| <b>Office Action Summary</b> | Application No.            | Applicant(s)     |
|                              | 10/566,878                 | VAN ES ET AL.    |
|                              | Examiner<br>Marsha M. Tsay | Art Unit<br>1656 |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

1) Responsive to communication(s) filed on 02 February 2006.  
 2a) This action is FINAL.                    2b) This action is non-final.  
 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

4) Claim(s) 1-7 and 9-20 is/are pending in the application.  
 4a) Of the above claim(s) 8 is/are withdrawn from consideration.  
 5) Claim(s) \_\_\_\_\_ is/are allowed.  
 6) Claim(s) 1-7 and 9-20 is/are rejected.  
 7) Claim(s) \_\_\_\_\_ is/are objected to.  
 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

9) The specification is objected to by the Examiner.  
 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
     Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
     Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).  
 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
 a) All    b) Some \* c) None of:  
 1. Certified copies of the priority documents have been received.  
 2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

|  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | Paper No(s)/Mail Date: _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date: _____ | 5) <input type="checkbox"/> Notice of Informal Patent Application |
|  | 6) <input type="checkbox"/> Other: _____                          |

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Applicant's election without traverse of Group I, claims 1-7, 9-20, to a recombinant gelatin-like polypeptide, in the reply filed on June 13, 2007 is acknowledged. Claim 8 has been withdrawn from further consideration by the Examiner because it is drawn to a non-elected invention.

Priority: The benefit date is August 5, 2003 for the purpose of prior art.

***Specification***

The disclosure is objected to because of the following informalities: on page 1 of the specification, the priority data needs to be updated with a cross-reference paragraph to related applications.

Appropriate correction is required.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-7, 9-20 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1, 9 recite Gly-Xaa-Yaa triplets. The claims are indefinite because neither the instant claims nor the specification define Xaa or Yaa.

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A broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim) is considered indefinite, since the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. See MPEP § 2173.05(c). Note the explanation given by the Board of Patent Appeals and Interferences in *Ex parte Wu*, 10 USPQ2d 2031, 2033 (Bd. Pat. App. & Inter. 1989), as to where broad language is followed by "such as" and then narrow language. The Board stated that this can render a claim indefinite by raising a question or doubt as to whether the feature introduced by such language is (a) merely exemplary of the remainder of the claim, and therefore not required, or (b) a required feature of the claims. Note also, for example, the decisions of *Ex parte Steigewald*, 131 USPQ 74 (Bd. App. 1961); *Ex parte Hall*, 83 USPQ 38 (Bd. App. 1948); and *Ex parte Hasche*, 86 USPQ 481 (Bd. App. 1949). In the present instance, claims 2 and 3, recite the broad recitation 3,000-80,000 Da and 3,000-15,000 Da, respectively, and the claims also recites 5,000-60,000 Da, 10,000-40,000 Da and 5,000-10,000 Da, 6,000-8,000 Da, respectively, which is the narrower statement of the range/limitation.

Regarding claims 2-4, 7, 10-11, 19-20, the phrase "preferably" renders the claim indefinite because it is unclear whether the limitation(s) following the phrase are part of the claimed invention. See MPEP § 2173.05(d).

Claims 5-6, 12-18 are included in this rejection because they depend on the above claims and fail to cure the defect.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-7, 9-20 are rejected under 35 U.S.C. 102(b) as being anticipated by Chang et al. (WO 0134801; IDS). Chang et al. teach vaccines comprising recombinant gelatin and method of producing such vaccines. Chang et al. teach a dried vaccine formulation comprising recombinant gelatin (p. 85 line 9, p. 86 line 29; claims 1) or lyophilized vaccines comprising recombinant gelatin as a stabilizer (p. 61 lines 35-38; claim 1). The recombinant gelatin can have a molecular weight range between 0 kDa to 350 kDa (p. 85 lines 22-26; claims 2-3). Chang et al. further teach that the recombinant gelatin can comprise a sequence selected from SEQ ID NOS: 15-25, 30, 31, 33, wherein said SEQ ID NOS. comprise a stretch of 10 or more consecutive repeats of Gly-Xaa-Yaa triplets and at least 20% of the amino acids are present in the form of consecutive Gly-Xaa-Yaa triplets (p. 86 lines 8-10, Seq. list pages 3-20; claims 1, 8). Chang et al. also teach a method of producing a composition comprising a vaccine and the recombinant gelatin (p. 88 lines 25-32; claim 9). In Example 4, Chang et al. teach the expression of a non-hydroxylated recombinant human gelatin sequence, SEQ ID NO: 24, which would inherently be free of a helical structure (p. 73 lines 5-10; claims 1, 6-8, 15-20). Further, Chang et al. teach the recombinant gelatins can possess particular ranges of molecular weights (p. 63 lines 30-32, example 1; claims 5, 12-14). While Chang et al. do not explicitly teach a glass transition temperature of greater than 180° C, this property is believed to be inherently present in the

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recombinant gelatin of Chang et al. because Chang et al. teach a recombinant gelatin-like polypeptide that meets the chemical and/or structural limitations of the instant recombinant gelatin-like polypeptide (claims 1, 4, 9, 10-11).

Claims 1-7, 9-20 are rejected under 35 U.S.C. 102(b) as being anticipated by Chang et al. (WO 0134646; IDS). Chang et al. teach recombinant gelatins, their compositions thereof, and methods of producing and using the same. The recombinant gelatin can be used as stabilizer in various pharmaceutical compositions, i.e. in drugs or vaccines (p. 61 lines 24-30; claim 1). The recombinant gelatin can have a molecular weight range between 0 kDa to 350 kDa (p. 91 lines 14-17; claims 2-3). Chang et al. further teach that the recombinant gelatin can comprise a sequence selected from SEQ ID NOS: 15-25, 30, 31, 33, wherein said SEQ ID NOS. comprise a stretch of 10 or more consecutive repeats of Gly-Xaa-Yaa triplets and at least 20% of the amino acids are present in the form of consecutive Gly-Xaa-Yaa triplets (p. 92 lines 34-35, Seq. list pages 3-20; claims 1, 8). Chang et al. also teach a method of using the recombinant gelatin to produce a composition comprising a drug and/or vaccine (p. 59-62; claim 9). In Example 4, Chang et al. teach the expression of a non-hydroxylated recombinant human gelatin sequence, SEQ ID NO: 24, which would inherently be free of a helical structure (p. 79 lines 31-36; claims 1, 6-8, 15-20). Further, Chang et al. teach the lyophilization of the recombinant gelatin and their molecular weight ranges (p. 77 example 1; claims 5, 12-14). While Chang et al. do not explicitly teach a glass transition temperature of greater than 180° C, this property is believed to be inherently present in the recombinant gelatin of Chang et al. because Chang et al. teach a

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recombinant gelatin-like polypeptide that meets the chemical and/or structural limitations of the instant recombinant gelatin-like polypeptide (claims 1, 4, 9, 10-11).

### ***Double Patenting***

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the “right to exclude” granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-7, 9-20 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-20 of copending Application No. 10567078 ('078). Although the conflicting claims are not identical, they are not patentably distinct from each other because both the instant claims and the '078 claims are drawn to a composition comprising a physiologically active and a recombinant and/or synthetic gelatin stabilizer and a method of preparing said composition.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Marsha M. Tsay whose telephone number is 571-272-2938. The examiner can normally be reached on M-F, 9:00am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Kathleen Kerr Bragdon can be reached on 571-272-0931. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

June 27, 2007

*M. Monshy*  
MARYAM MONSHPOURI, PH.D.  
PRIMARY EXAMINER